## REMARKS/ARGUMENTS

### I. Status of the Claims

Claims 1-17 were originally filed and subsequently canceled. Claims 18-65 were added. As the result of a restriction requirement, claims 27-65 have been withdrawn. Claims 18, 19, and 23-26 are currently amended. Claims 18-26 are under examination.

### II. Support for the Present Amendment

The present amendment to claims 18 and 23-26 deletes the phrase of "an immunogenic peptide, native protein fragment or particle" and substitutes the phrase with "the fusion protein." Support for the amendment can be found in the specification, examples, figures, and claims as originally filed. For example, support can be found on, *e.g.*, page 11, lines 1-12, where it is recited that:

> Alternatively, recombinant DNA technology may be employed wherein a nucleotide sequence which encodes an immunogenic peptide of interest is inserted into an expression vector, transformed or transfected into an appropriate host cell and cultivated under conditions suitable for expression. . . . Thus, fusion proteins which comprise one or more peptide sequences of the invention can be used to present the appropriate T cell epitope.

(Emphasis added). This substitution thus adds no new matter.

Claim 19 is further amended to reword the claim from "the polynucleotide is comprised by an expression vector" to "[a]n express vector comprising the polynucleotide." No new matter is added.

### III. Priority

The Examiner held that the present application is not entitled to priority to USSN 08/305,871 ("the '871 application"), alleging the '871 application provides no support for pending claims 18-26.

Applicants respectfully disagree. Amended claims 18, 19, and 23-26, and previously added claims 20-22 are drawn to polynucleotides encoding fusion proteins

comprising at least one pan DR binding peptide selected from the formula $R_1$-$R_2$-$R_3$-$R_4$-$R_5$. The description of the recited pan DR binding peptides can be found, *e.g.*, on page 4, lines 16-28 of the '871 application.

The description of a polynucleotide sequence encoding a polypeptide comprising the recited peptide sequence can be found, *e.g.*, on page 11, lines 1-12 of the '871 application (see quoted paragraphs in the last section).

The same paragraph and the section on page 11, lines 18-22, among other sections in the '871 application, also support amended claim 19, "[a]n expression vector comprising the polynucleotide of claim 18."

Claim 20, reciting "multiple pan DR peptides," finds support, *e.g.*, on page 17, lines 28-30.

Claims 21 and 22, reciting "homopolymer" and "heteropolymer" of pan DR peptides, find support, *e.g.*, on page 19, lines 27-36.

Amended claim 23, reciting "heteropolymer with repeating units," finds support, *e.g.*, on page 19, lines 35-36.

Amended claim 24, reciting "T helper peptide," finds support, *e.g.*, on page 19, line 35.

Amended claim 25, reciting "antibody-inducing peptide," finds support, *e.g.*, on page 10, lines 12-14.

Amended claim 26, reciting "CTL-inducing peptide," finds support, *e.g.*, on page 10, lines 10-12.

As such, Applicants submit that pending claims 18-26 are fully supported by the '871 application. The present application is therefore entitled to priority to the '871 application, filed September 14, 1994.

## IV. Oath/Declaration

The Examiner also stated that the oath/declaration was defective for non-initialed alterations. Applicants hereby submit a new oath/declaration pursuant to 37 C.F.R. §1.67(a).

## V. Specification

The Examiner objected to the specification, alleging that it provides no support for newly added claims. Applicants note that the present specification is identical to that of the '871 application, except the first paragraph of the specification. Therefore, specific support for pending claims 18-26 identified above with respect to the '871 application also applies to the present application. The objection to the specification for lack of support for the claims should thus be withdrawn.

## VI. Claim Rejections

A. 35 U.S.C. §112 First Paragraph

The Examiner rejected claims 18-26 under 35 U.S.C. §112 first paragraph, alleging that the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection.

As amended, the pending claims are directed to polynucleotides encoding fusion proteins comprising at least one pan DR binding peptide selected from the formula $R_1$-$R_2$-$R_3$-$R_4$-$R_5$. As discussed in the previous section, the present claims are fully supported by both the present and priority specifications.

The amended claims fully comply with the requirements for written description of a chemical genus as set forth in *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). As described by the Federal Circuit in *Lilly*, "[a] description of a genus of cDNAs may be achieved by means of . . . a recitation of structural features common to the members of the genus . . . ." *Lilly*, 43 USPQ2d at 1406. Furthermore, the court in *Fiers v. Revel* stated that an adequate written description "requires a precise definition, such as by structure,

formula, chemical name, or physical properties." *See Fiers*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Moreover, a patent application should "clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The present claims meet these criteria.

The pending claims set forth polynucleotides that encode fusion polypeptides with common structural features, *e.g.*, comprising at least one pan DR binding peptide selected from the formula $R_1$-$R_2$-$R_3$-$R_4$-$R_5$. The application sets forth those pan DR sequences that are recognized by a large number of different MHC II alleles. The examples demonstrate that several different sequences within the scope of the pan DR sequence recitation bind MHC II molecules. Moreover, the pan DR sequences taught in the specification identify precisely which amino acid positions within the motif can be changed to maintain activity.

As described above, the application supports fusion of the pan DR peptide sequences to any immunogenic sequence, including antibody-inducing sequence, as well as CTL or HTL sequence. Those of ordinary skill in the art at the time the priority application was filed would have had knowledge of the myriad appropriate sequences which the application teaches may be fused to the pan DR peptide sequences of the invention. Accordingly, the law does not require that the specification recite the great number of sequences to which the pan DR sequence may be fused. By providing a detailed description of commonly shared structural features (i.e., pan DR peptide sequences) of the claimed genus of polynucleotides, the specification adequately describes the recited pan DR sequences within the standards set forth by the Federal Circuit in *Lilly*, *Fiers* and *Vas-Cath*.

Accordingly, withdrawal of the rejection is respectfully requested.

B. 35 U.S.C. §102

The Examiner further rejected claims 18-26 under 35 U.S.C. §102(a), alleging that the claims are anticipated by WO 99/58658. Applicants respectfully traverse the rejection.

As discussed above, the present application is entitled to priority to USSN 08/305,871, which was filed September 14, 1994. Thus, WO 99/58658, which has the priority

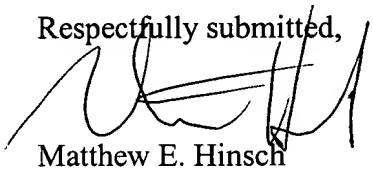
date of May 13, 1998, is not available as a 102(a) prior art reference. As such, Applicants respectfully request that the anticipation rejection be withdrawn.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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